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MAR 26 2002

James L. Wilmer, Ph.D.
Director, Scientific Affairs
Market America, Inc.
1302 Pleasant Ridge Road
Greensboro, North Carolina 27409

Dear Dr. Wilmer:

This is in response to your letter of January 16, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product Isotonix Coenzyme Q10 uses the claim "Helps maintain normal blood pressure...." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to your claim about control of blood pressure; that is, a claim that does not establish that the claim is about blood pressure that is already within normal limits implies that the product is intended to treat hypertension, which is a disease.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

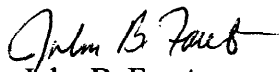
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Page 2 - Dr. James L. Wilmer

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Atlanta District Office, Office of Compliance, HFR-SE140

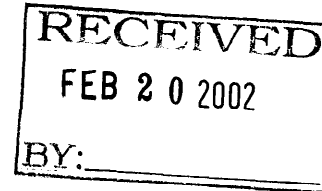
1302 Pleasant Ridge Road
Greensboro, North Carolina 27409
Voice: 336.605.0040



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E-Mail: mamerica@morebv.com
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12344
January 16, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S. W.
Washington, D. C. 20204



Dear Sir/Madam:

I have enclosed notification forms that are intended to comply with Section 6 of the Dietary Supplement Health and Education Act of 1994 and Rule 21 C.F.R. §101.93. One dietary supplement called *Isotonix Coenzyme Q₁₀* is discussed. I have listed the structure-function statements found on the product label and associated support literature, and have identified the product ingredients that are the subject of the statements.

Thank you.

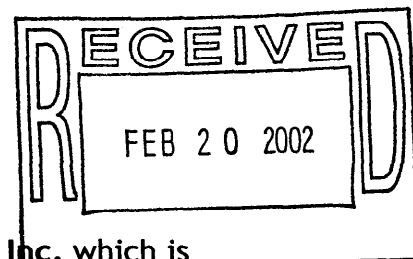
Sincerely,

A handwritten signature in cursive script that reads "James L. Wilmer".

James L. Wilmer, Ph. D.
Director, Scientific Affairs

Enclosures: 1 original and 2 copies

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93



This notification is being filed on behalf of **Market America, Inc.** which is the distributor of the product bearing the statements identified in this notification. Its business address is **1302 Pleasant Ridge Road, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Isotonix Coenzyme Q₁₀**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: [Coenzyme Q₁₀] "Helps protect and strengthen the cardiovascular system"—Spec Sheet

Statement 2: [Coenzyme Q₁₀] "Helps maintain normal blood pressure without side effects"—Spec Sheet

Statement 3: [Coenzyme Q₁₀] "Helps promote periodontal health" —Spec Sheet

Statement 4: [Coenzyme Q₁₀] "Helps energize your body's cells and increase stamina and endurance"—Spec Sheet

Statement 5: [Coenzyme Q₁₀] "Helps reduce weight naturally by speeding up the metabolism of fat"—Spec Sheet

Statement 6: [Coenzyme Q₁₀] "Revitalizes the immune system's natural defenses"—Spec Sheet

Statement 7: "An Advanced System For Cellular Maintenance" —Bottle Label

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

Statement Number(s)	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
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- 1.—7. Isotonix Coenzyme Q₁₀ is composed of the following ingredients: coenzyme Q₁₀, vitamin E, lipase, vitamin B₂, potassium; other ingredients include: fructose, glucose, citric acid, silica, calcium sulfate, pectin, maltodextrin, and natural lemon-lime flavor.

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.- 6.	Isotonix Coenzyme Q ₁₀	Spec Sheet
7.	Isotonix Coenzyme Q ₁₀	Bottle Label

I, James L. Wilmer, am authorized to certify this Notification on behalf of Market America, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Market America, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: JANUARY 16, 2002

By: James L. Wilmer

James L. Wilmer, Ph. D.
Director, Scientific Affairs
Market America, Inc.